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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,118	03/24/2005	Frank Cuttitta	4239-66904-02	6689

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,118	CUTTITTA ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/24/05; 6/6/05; 6/29/05; & 7/5/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 10-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 10-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 3/24/05 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/24/05; 6/6/05; 6/29/05; & 7/5/05.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 3/24/05 wherein claims 6-9 are canceled and claim 10 is amended.

Note: Claims 1-5 and 10-27 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to compositions and uses thereof comprising a peptide AM as set forth in independent claims 1, 5, 14, and 22.

112 SECOND PARAGRAPH REJECTIONS

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 5, 10-21, and 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4: The claims as written are ambiguous because it appears as if essential steps are missing from independent claim 1. In particular, the claim is directed to a method of vasoconstricting blood vessels wherein the peptide is administered only. In other words, there are no steps present to enable one to determine if the blood vessels have successfully been constricted or not.

Claim 5, 10-21, and 25-27: The claims as written are ambiguous because it is unclear whether the peptide AM (11-22) is that of SEQ ID No. 4 or some other sequence (i.e., that of human AM as set forth in Watanbe et al, Biochemical and Biophysical Research Communication, 1996, 219, 59-63 or the AM sequence as set forth in Kitamura et al 2001, Peptides, 22, 1713-1718, both references were listed on Applicant's information disclosure statement).

Claim 14: The claim as written is ambiguous because there are not method steps to for the screening method. It appears as if essential steps are missing from the claim. The method simply states that one has a method of screening comprising determining whether a compound inhibits AM (11-22), but does not disclose how one goes about screening compounds (i.e., comparing a control with a test group).

Claims 20 and 24: The claim is ambiguous because the term 'small' is a relative term. Thus, one cannot ascertain what Applicant is intending by the phrase 'small molecule'.

Claim 22: The claim as written is ambiguous because it appears as if essential steps are missing from the claim. The method discloses just administering the peptide compound, but does not disclose how one determines if the blood vessels are dilated or not.

103 REJECTIONS

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 5, 10, 13-18, 21-25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitamura et al (Peptides, 2001, Vol. 22, pages 1713-1718, document listed on IDS) in view of Fritzberg et al (US Patent No. 5,175,343).

Kitamura et al disclose adrenomedullin (11-26) that is supposedly a potent hypotensive peptide. In addition, Kitamura et al disclose that AM (11-26) is a major component of immunoreactive AM and shows pressor activity (see entire document, especially, abstract). In the materials and methods section (page 1714), AM and hAM peptides are disclosed. The radioimmunoassay was performed. Monoclonal antibody for the ring structure of AM was prepared. The preparation of peptide extract involved purification of AM peptide. The pressor effect of AM (11-26) was examined using rats. A catheter was inserted into the right femoral vein for administration of the maintenance solution and peptides. After equilibration for at least 60 minutes, synthetic AM (11-26) dissolved in 100 microliters of saline or 100 microliters of saline (control) was injected intravenously into the subject (pages 1714-1715, bridging paragraph; page 1716, columns 1-2, bridging paragraph). Kitamura et al concluded that AM (11-26) has potent hypertensive activity (page 1718, column 1, second complete paragraph). However,

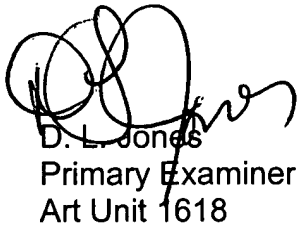
Kitamura et al fails to disclose the specific peptide sequence being claimed by Applicant.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a peptide AM (11-22) for vasconstricting blood vessels because Kitamura et al disclose peptide AM (11-26) that is a vasopressor wherein amino acid 11-22 differ at position 19, Kitamura et al disclose a Val instead of Ala (see Figure 3, page 1716). However, a skilled practitioner in the art would recognize that the replacement of one conservative amino acid with another would not drastically alter the overall properties of the peptide. In addition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a kit comprising peptide AM (11-22) because of the ever present need for such kits in medical facilities (i.e., hospitals, clinics, etc.) in order to readily obtain results. In addition, the generating of a kit is well known in the art. For examples, one of ordinary skill would be able to apply the techniques disclosed in Fritzberg et al (US Patent No. 5,175,343, column 16, line 37 through end of patent) for generating various types of kits depending upon the desired need.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



D. L. Jones
Primary Examiner
Art Unit 1618

February 16, 2007